

REMARKS

Claims 1-8, 12-36, 54-58, 62, 63 and 65-67 presently appear in this case. Claim 19 has been withdrawn from consideration. Claims 9-11, 37-53, 59-61 and 64 have been cancelled. No claims have been allowed. The official action of January 15, 2003 has now been carefully studied. Reconsideration and allowance are hereby respectfully urged.

Briefly, the present invention relates to genetically stable, transformed *Lemnaceae* plant and progeny thereof, the plants being preferably transformed with a heterologous DNA of interest integrated into its chromosome. The invention further relates to a method for the stable genetic transformation of *Lemnaceae* plants, including the whole plants, plant tissue or callas, by inoculating *Lemnaceae* tissue with *Agrobacterium* containing a transforming DNA molecule having a nucleotide sequence of interest and co-cultivating the tissue with the *Agrobacterium* to produce the stably transformed *Lemnaceae* tissue. The invention further relates to a method for production of the product of interest by culturing the stably transformed *Lemnaceae* plant and isolating and purifying the heterologous product produced thereby.

It should be noted that, as filed, the present application was denominated a §371 national stage of

PCT/IL98/00487 which PCT claimed priority under 35 USC 119 of PCT/IL97/00328 filed October 10, 1997, which PCT application was a foreign application by virtue of the fact that it designated many states other than the United States, as well as the United States (see the declaration filed August 22, 2000, which lists the 1997 PCT application under the foreign priority benefits section).

Applicant hereby changes the manner in which the benefit of the 1997 PCT application is claimed. As the 1997 application can be considered to be a U.S. application, as it designated the United States, and as the 1998 application adds additional subject matter (for example, example 28 is in the 1998 application, published as WO 99/19498, and not in the 1997 application, published as WO 99/19497), applicant hereby designates the PCT application, of which the present application is the national phase under 35 USC §371, as a continuation-in-part of the 1997 PCT application designating the United States. Thus, benefit is claimed under 35 USC 120 and not 35 USC 119.

Attached hereto is an application data sheet that supersedes the declaration as originally filed insofar as the benefit information is concerned. Acknowledgement of this change of benefit and issuance of a corrected official filing receipt to correctly show this amended benefit information is

respectfully urged. It should be noted that as the present application is a §371 of an international application filed on October 8, 1998, the time periods as set forth in 37 CFR 1.78 (2)(ii) are inapplicable; see 37 CFR 1.78 (2)(ii)(C).

It is noted that the examiner has found applicant's previous traversal of the restriction requirement to be convincing with respect to claims 20-24, 62 and 63, but it was considered proper and therefore made final with respect to claims 19, 37-53, 59-61 and 64. This restriction requirement is again respectfully traversed.

Claims 37-53, 59-61 and 64 have now been deleted without prejudice toward the continuation of prosecution thereof in a divisional application. However, it is urged that claim 19 should be examined with dependent claims 20-22 that the examiner considers to be directed to the same invention as group I. Claim 19 certainly must be considered to be patentably indistinct from claims 20-22. Claim 20 specifies that the plant is a *Lemnaceae* plant. Claims 21 and 22 do not require that the claims be a *Lemnaceae* plant, but specify the size of the particles into which the plant is cut. Certainly claims 19 and 21 and claims 19 and 20 share the same general inventive concept. Accordingly, it is urged that claim 19 be examined with claims 20-22, and the other claims considered to be a part of group I. Reconsideration and

withdrawal of the restriction requirement to this extent is therefore respectfully urged.

The examiner states that the specification fails to comply with the sequence rules, as the nucleotides that appear on page 28 (presumably the examiner intended to refer to page 25) need to be submitted as part of a sequence listing.

Attached hereto is a sequence listing in full compliance with the applicable rules, thus obviating this requirement.

Applicants have added into the present specification a new paper copy Sequence Listing section according to 37 C.F.R. §1.821(c) as new page 1. Furthermore, attached hereto is a 3 1/2" disk containing the "Sequence Listing" in computer readable form in accordance with 37 C.F.R. §1.821(e).

Applicants have amended the specification to insert SEQ ID Nos, as supported in the present specification.

The following statement is provided to meet the requirements of 37 C.F.R. §1.821(f) and 1.821(g).

I hereby state, in accordance with 37 C.F.R. §1.821(f), that the content of the attached paper and computer readable copies of the sequence listing are believed to be the same.

I hereby also state, in accordance with 37 C.F.R. §1.821(g), that the submission is not believed to include new matter.

The examiner has required applicant to submit acceptable corrected drawings within the time period set in the official action in order to correct the informalities noted by the draftsperson on form PTO 948. The examiner states that failure to take corrective action within the set or extended period will result in abandonment of the application. This requirement is respectfully traversed.

First of all, attached hereto is another copy of the formal drawing. The left margin is now appropriate. It is urged, however, that the character of the lines, numbers and letters are sufficiently plain and legible to comply with 37 CFR 1.84 (i) and (p). It should be noted that this drawing was accepted for publication by the PCT and it can equally be accepted for publication in the United States. It can be reproduced and it is understandable.

Furthermore, 37 CFR 1.85 (a) to which the examiner refers and states that objections to the drawings will not be held in abeyance, is not applicable to the present case. This change was effective for applications filed after November 7, 2000. The present application was filed prior to November 7, 2000, and therefore is not subject to publication in the

United States, and is subject to the old rule 37 CFR 1.85, which permits objections to the drawing to be held in abeyance until after the notice of allowance is issued. If the attached drawing is not acceptable, it is requested that any requirement for new drawing be held in abeyance pursuant to 37 CFR 1.85 as is effective for the present application.

Claims 2-8, 13-18, 21, 22, 24, 26-35, 56, 57, 62, and 63 have been objected to for a number of informalities. The examiner states that the article "A" in line 1 of the claims should be --The--. Furthermore as to claims 4 and 5, the examiner states that claim 4 is in improper form because a multiple dependent claim should refer to other claims in the alternative only. This rejection is respectfully traversed.

With respect to claim 4, this claim has been amended as suggested by the examiner, thus obviating this part of the rejection. With respect to the examiner's objection to the article used at the beginning of the claim, the examiner has no authority to require such a change. Applicants have a right to claim their invention in the manner in which they see fit. Unless the examiner wishes to state a rejection under some statute or wishes to cite some authority for the alleged objection, applicant will continue to claim the invention as applicant's attorney has consistently claimed inventions for the last thirty years without objection by any examiner. The

examiner does not require the word "the" as the first word of claim 1, as claim 1 is not included in this rejection. If claim 2 were written into independent form, would the examiner require the word "the" as the first word of that claim? A dependent claim is merely a shorthand way of writing an independent claim. If "A" is permissible for independent claims, as this examiner found acceptable for claim 1, then it must be acceptable also for dependent claims. This language was also found acceptable at MPEP 608.01(n) under "A."

Acceptable Multiple Dependent Claim Wording." This objection is inappropriate and unsupportable and must be withdrawn. Reconsideration and withdrawal thereof is therefore respectfully urged.

Claims 9-11 have been rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

Claims 9-11 have now been deleted, thus obviating this rejection.

Claims 1, 4-7, 9-18, 20-23, 26-36, 54-58, 62 and 63 have been rejected under 35 USC 112, second paragraph, as being indefinite. The examiner states that in claim 1 the recitation "and progeny thereof" renders the claim indefinite as it is not clear if the progeny contains nucleic acids that

were transformed into the parent plant. This part of the rejection is respectfully traversed.

The examiner's attention is invited to the definition of "stable transformation" at page 3, lines 25 and 26, of the present specification. This term denotes such a genetic transformation "which is heritable to future generations of the transformed plant". As claim 1 is directed to a genetically stable transformed *Lemnaceae* plant, then by definition the foreign DNA is heritable to the progeny. Thus, claim 1 is not indefinite. Reconsideration and withdrawal of this part of the rejection is respectfully urged.

The examiner states that in claim 4, there is improper antecedent basis for the recitation "antibiotic resistant transformed *Lemnaceae* plant."

Claim 4 has now been amended in order to obviate this part of the rejection.

The examiner states that in claim 6 there is improper antecedent basis for the recitation "herbicide resistant transformed *Lemnaceae* plant".

Claim 6 has now been amended in a manner to obviate this part of the rejection.

The examiner states that in claim 7, the recitation "being tolerant to oxynil herbicides ..." renders the claim

indefinite, as the claim does not indicate that the plant has been transformed with any herbicide resistant gene.

Claim 7 has now been amended so as to obviate this problem.

In claims 9-10 the examiner states that the claims provide for the use of the plant of claim 1.

Claims 9 and 10 have now been deleted, thus obviating this part of the rejection.

The examiner states that in claim 12, the final recited step is not consistent with the preamble.

Claim 12 has now been amended in order to insert antecedent basis for the language noted by the examiner, thus obviating this part of the rejection.

The examiner states that in claims 14, 16 and 26, the claims are Markush type that employ improper Markush terminology.

Claims 14, 16 and 26 have now been amended in order to obviate this part of the rejection.

The examiner states that in claims 20-23, 62 and 63, the claims are indefinite for being dependent upon a non-elected claim.

For the reasons explained hereinabove, it has been requested that claim 19 be re-inserted into the present application. Claim 19 is not drawn to an invention with a

different general inventive concept from claims 20-23, 62 and 63 which depend therefrom. Accordingly, if claim 19 is reinserted into the case, this part of the rejection will be obviated. If not, applicant requests that this rejection be held in abeyance until a final decision is reached as to the status of claim 19; see 37 CFR §1.144.

The examiner states that claim 21 is not clear as to whether all the particles share an average size and what is encompassed by "above about".

Claim 21 has now been amended in order to obviate this rejection.

The examiner states that claim 22 is indefinite as to the metes and bounds of the term "average".

Claim 22 has also been amended in order to obviate this part of the rejection.

The examiner states that claims 27, 29 and 34 are indefinite in the recitation "booster medium" as it is not clear what this medium consists of.

These claims have now been amended to specify what the booster medium consists of, thus obviating this part of the rejection.

The examiner states that claim 29 has no antecedent basis for booster medium.

The dependency of claim 29 has now been corrected, thus obviating this part of the rejection.

The examiner states that in claims 30 and 32, there is insufficient antecedent basis for "the fresh cell suspension".

Claims 30 and 32 have now been amended to correct their dependency, thus obviating this part of the rejection.

The examiner states that there is insufficient antecedent basis for "the medium" in claim 33 and it is unclear what is "medium caffeine".

Claim 33 has now been amended in order to obviate this rejection.

The examiner states that claim 36 is indefinite for being dependent upon a non-elected claim.

As discussed above with respect to the rejection of claims 20-23, 62 and 63, it has been urged hereinabove that the unity of invention requirement be withdrawn with respect to claim 19. If this is done, this rejection will be obviated. If not, it is requested that this rejection be held in abeyance and claim 36 will be amended to delete reference to claim 19.

The examiner states that in claim 54, the recitation "coding said product" is indefinite.

The word "coding" has now been amended to read "encoding", thus obviating this part of the rejection.

The examiner states that claim 63 is indefinite in "an average diameter for about 150  $\mu\text{m}$  - 750  $\mu\text{m}$ ".

Claim 63 has now been amended as suggested by the examiner, thus obviating this part of the rejection.

Accordingly, reconsideration and withdrawal of the entire 35 USC 112, second paragraph, rejection is respectfully urged.

Claims 1-8 and 36 have been rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement thereof. The examiner states that the claims are broadly drawn toward any genetically stable transformed *Lemnaceae* plant and progeny thereof. However, the examiner states that the specification does not describe all stably transformed *Lemnaceae* plants and their progeny, but only *Agrobacterium* mediated methods to transform *Lemnaceae* plants. The examiner states that there are insufficient examples of transgenes and the specification does not encompass all types of transgenes. The examiner states that the specification does not describe any plants that were transformed by non-*Agrobacterium* mediated methods. This rejection is respectfully traversed.

Claim 1 is directed to a product. Applicant was the first one to be able to achieve such a product. When claiming a product, it is not necessary to recite the method by which it is made. The examiner here is apparently requiring a product-by-process claim in order to specify that the product is made using *Agrobacterium*. Adding such a process limitation would not distinguish the claim from prior art made in another way. Product-by-process claims are permissible, but they are never required if the product can adequately be described by characterization as opposed to its process of making, as is the case here. If applicant claimed a novel protein, but only one way of making it, would the examiner require that the product claim to the protein specify the method of making? If applicant claimed a novel chemical compound, would the examiner require that the sole process of making that compound be inserted into the claim, even if the specification indicates that there is only one known method of making it? The answer to both the previous rhetorical questions is no. Similarly, there should not be a requirement that claim 1 require the process of making the product. It should be noted that this part of the rejection should not be applicable to claim 36, as claim 36 requires that it be made by the use of an *Agrobacterium*. Furthermore, new claim 66 has now been added which specifies that the transformation is *Agrobacterium*

mediated and thus should not be subject to this rejection.

Reconsideration and withdrawal of this part of the rejection with respect to claims 1-8 is respectfully urged.

With respect to the breadth of the transgene that is added to the plant, the specification recites dozens of examples. Page 3, lines 27-32, states that the foreign DNA may be of any origin, and may comprise coding sequences and/or control sequences, etc. Examples are set forth at page 4, lines 14-18, the paragraph bridging pages 4 and 5, and page 5, lines 1-9. See also page 9, line 10, to page 12, line 23. Many examples of different foreign DNA are exemplified. If the colored marker gene is expressed, then there is no reason to believe that any other foreign DNA would not also be expressed. It is noted that the examiner had no problem with the breadth the transgene claimed in the Stomp patent no. 6,040,498 examined by this examiner and cited against the present application. Sufficient examples are given to allow one of ordinary skill in the art to believe that the entire genus will be operable and that applicant is in possession of the entire genus. Reconsideration and withdrawal of this rejection is therefore respectfully urged.

Claim 3 has been rejected under 35 USC 112, first paragraph, for failing to comply with the enablement requirement thereof. The examiner states that the claimed

strain 8717 is essential to the invention and must be obtainable by a repeatable method or otherwise readily available to the public. Otherwise, it must be deposited. This rejection is respectfully traversed.

The public availability of this strain is still being investigated. It was not invented by the present inventors. If it is determined that is not publicly available, then a depository statement will be made. In the meantime, it is requested that this rejection be held in abeyance pursuant to 37 CFR 1.111(b) until allowable subject matter is indicated in the case.

Claims 1, 2, 4-10, 12-16, 18, 20, 25, 26, 28, 36 and 54-57 have been rejected under 35 USC 102(e) as being clearly anticipated by Stomp in light of Stachel. This rejection is respectfully traversed.

As the subject matter of Stomp on which the examiner relies appears in the claims of Stomp, this rejection cannot be overcome by filing a declaration under 37 CFR 1.131. If the examiner does not agree with this statement, and believes that the rejection of any of the claims is based only on what is disclosed in Stomp and not what is claimed in Stomp, then it is respectfully requested that the examiner specify same and applicant will file an appropriate declaration.

Insofar as the examiner considers that the present claims are not patentably distinct from the claims of Stomp, this can only be overcome by means of an interference. Accordingly, applicant hereby requests an interference with patent 6,040,498 of Stomp et al. Attached hereto is a statement under 37 CFR 1.607 and 1.608(a) complying with the necessary regulations with respect thereto. Accordingly, Reconsideration and withdrawal of this rejection in light of the attached request for an interference is respectfully urged.

Claim 3 has been rejected under 35 USC 102(e) as anticipated by or, in the alternative, under 35 USC(a) as obvious over Stomp. This rejection is respectfully traversed.

As the examiner does not consider claim 3 to be patentably distinct from the subject matter of claim 1 and as the subject matter of claim 1 is not patentably distinct from the subject matter of claim 20 of Stomp, this rejection as well is made moot by the attached request by applicant for interference with the Stomp patent.

Claims 1, 2, 4-10, 12-18, 20-30, 32, 34-36, 54-58, 62 and 63 have been rejected under 35 USC 103(a) as being unpatentable over Stomp in view of a number of secondary references. This rejection is respectfully traversed.

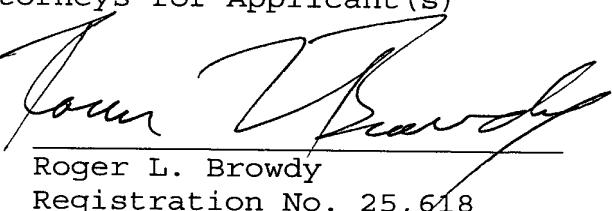
If Stomp is not available as a reference, then this rejection must fall. As applicant invented the present invention prior to Stomp, Stomp is not available as a reference. This will be established in the interference proceeding which applicant is requesting herewith. Accordingly, this rejection as well is moot in light of the attached request for an interference.

It is submitted that all the claims now present in the case are now in condition for allowance, pending declaration of an interference between the present application and the Stomp patent. Reconsideration and withdrawal of all the rejections of record and institution of an interference between the present application and Stomp as per the attached request under 37 CFR 1.607 is earnestly solicited.

Respectfully submitted,

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